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SECTION 5. 510(K) SUMMARY

Summary of Safety and Effectiveness

JUN 27 2007

In accordance with 21 CFR 807.92, the following information constitutes Artimplant AB's summary for the Artelon® STT Spacer.

SUBMITTER'S NAME:	Artimplant AB
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DATE OF SUBMISSION:	07/10/2006

1. **Identification of device**
   Proprietary Name: Artelon® STT Spacer
   Common Name: Trapezium Polymer Prosthesis
   Classification Status: 888.3770
   Product Code: KYI

2. **Equivalent devices**
   We believe that the ARTELON STT Spacer is substantially equivalent to:
   K040070 Artelon® CMC Spacer Artimplant AB
   Pre-amendment device, Swanson Trapezium Implant, Dow Corning Wright

3. **Description of the Device**
ARTELON STT Spacer is a woven one-piece, L-shaped implant made of ARTELON, a polycaprolactone based polyurethaneurea.

4. **Indications for use**
ARTELON STT Spacer is intended to be implanted into the scaphotrapeziotrapezioidal (STT) joint as an interpositional spacer between the scaphoid bone and the trapezial-trapezioid bones. The device is intended to be used in thumb disabilities caused by osteoarthritis.

5. **Comparison to predicate device.**
The predicate device, Swanson Trapezium Implant (pre-amendment device) is similar to ARTELON STT Spacer in that it is used as a space filling device for treatment of osteoarthritis and articulates against the STT joint. The ARTELON CMC Spacer is also a spacing device, but intended for implantation in the CMC-1 joint as an interpositional spacer.

All three devices are made of elastomers. The ARTELON STT Spacer is made of the same material, ARTELON, and is of the same basic design as the ARTELON CMC Spacer (K040070).

All devices are supplied sterile and for single patient use.

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6. Discussion of performance testing.

A collection of tests have been successfully completed. The results from the performance testing demonstrate that ARTELON STT Spacer provides appropriate assurance of safety and effectiveness.

7. Conclusion

Based on comparison to the predicate devices, ARTELON STT Spacer is substantially equivalent to the legally marketed devices and presents no new concerns of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Artimplant AB
c/o M Squared Associates, Inc.
Ms. Terry Sheridan Powell
Senior Project Manager
719 A Street NE
Washington DC 20002

JUN 27 2007

Re: K061956
Trade/Device Name: Artelon® STT Spacer
Regulation Number: 21 CFR 888.3770
Regulation Name: Wrist joint carpal trapezium polymer prosthesis
Regulatory Class: Class II
Product Code: KYI
Dated: May 15, 2007
Received: May 17, 2007

Dear Ms. Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

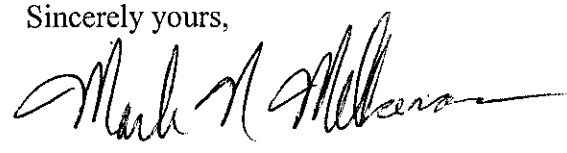
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or 240-276-3150 or on the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K061956

Device Name: ARTELON STT Spacer

Indication For Use:

ARTELON STT Spacer is intended to be implanted into the scaphotrapeziotrapezioidal (STT) joint as an interpositional spacer between the scaphoid bone and the trapezial-trapezioid bones. The device is intended to be used in thumb disabilities caused by osteoarthritis.

Prescription Use __X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

K061956

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061956